



Texas Department of State Health Services

DRUGS AND MEDICAL DEVICES GROUP WEB SITE:
<http://www.dshs.state.tx.us/dmd/>

**ISSUANCE OF CERTIFICATES OF FREE SALE AND SANITATION AND/OR
CERTIFICATES OF ORIGIN AND SANITATION
(25 Texas Administrative Code, §§229.301 – 229.307)**

§229.301. Purpose. These sections set out the requirements for the Department of State Health Services (department) to issue a certificate of free sale and sanitation and/or a certificate of origin and sanitation. Certificates are issued only to Texas licensed manufacturers and/or distributors with product physically present in Texas (and therefore available for inspection by the department) for the purpose of exporting products from the United States into other countries. Products shall be manufactured in Texas and/or distributed, warehoused, and sold from Texas. Certificates for cosmetics can only be issued after the department has inspected the Texas manufacturing and/or warehousing facility. Certificates for meat and poultry products can only be issued by the United States Department of Agriculture (USDA).

§229.301. Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Certificate of free sale and sanitation--A certificate issued by the department, which certifies that the distributor of the food, drugs, cosmetics, medical device products, dietary supplements, milk and dairy products, or molluscan shellfish products listed in the document is duly authorized to distribute the products and that the products can be sold freely to the public in Texas, and that the distributor is in substantial compliance with Texas Health and Safety Code, Chapters 431, 435, 436, or 440, depending on the product (the Acts), and with 25 Texas Administrative Code, Chapters 217, 229, or 241 (the Rules), as determined by the department.

(2) Certificate of origin and sanitation--A certificate issued by the department, which certifies that the product(s) listed in the document originate from, are manufactured in, produced in or grown in the State of Texas and can only be issued to a Texas manufacturer.

(3) Common or usual name--The common or usual name of a food shall accurately identify or describe in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The "common or usual name" shall comply with all state and federal regulations, including Title 21, Code of Federal Regulations (CFR), §102.5.

(4) Current inspection--An official inspection of an establishment conducted within the time specified in §229.303(b) of this title (relating to Minimum Requirements), or immediately preceding a request for certificate of free sale and sanitation and/or a certificate of origin and sanitation.

(5) Currently licensed--Establishments regulated by the department under the Texas Health and Safety Code (Texas Food, Drug, and Cosmetic Act, Texas Dairy Products Act, Texas Aquatic Life Act, and Frozen Desserts Manufacturer Licensing Act,) which possess a current, valid license.

(6) Custom certificate--A certificate of free sale and sanitation or certificate of origin and sanitation with additional verbiage requested by the applicant. The verbiage may be specific to the requirements of the receiving country and/or specific information about the product(s) listed on the certificate(s).

(7) Department--The Department of State Health Services.

(8) Private Labeler--A firm that distributes a product under a custom label, trade name, private label, or its own label, and assumes full responsibility for compliance with all applicable laws and regulations, and the product is manufactured and labeled by another licensee and/or registered establishment. For purposes of this regulation, regardless of license type issued, a private labeler can only be issued a certificate of free sale and sanitation.

(9) Properly labeled--Products in compliance with applicable state and federal statutes and regulations as listed in subparagraphs (A) - (D) of this paragraph and in accordance with the Texas Food, Drug and Cosmetic Act, Texas Health and Safety Code, Chapter 431.

(A) Title 21, CFR, Part 101, Food labeling (relating to labeling of food, beverages, and dietary supplements).

(B) Title 21, CFR, Part 201, Labeling (relating to labeling of drugs), and Title 21, CFR, Parts 310 and 328 - 369 (relating to monograph labeling requirements).

(C) Title 21, CFR, Parts 701 and 740, Cosmetic labeling.

(D) Title 21, CFR, Part 801, Labeling (relating to labeling of medical devices)

§229.303. Minimum requirements.

(a) Current license. All establishments, except those exempt from licensing by law, shall be currently licensed by the department and shall be in substantial compliance with the Acts and the Rules as they apply to each specific type of operation.

(b) Current compliant inspection. All establishments shall have a current compliant inspection as follows:

(1) distributors or wholesalers of foods, drugs, or medical devices, within 24 months of application;

(2) manufacturers of foods, drugs, or medical devices, within 12 months of application;

(3) manufacturers, distributors, or wholesalers of cosmetic products, within 24 months of application;

(4) producers, processors, and distributors of milk or dairy products, within 3 months of application; and

(5) producers or distributors of molluscan shellfish, within 3 months of application.

(c) Private Labelers. Private Labelers can only apply for and receive a certificate of free sale and sanitation in the name of the private labeler. Private labelers are responsible for purity and labeling of products and for compliance with all applicable laws and regulations. For purposes of this regulation, regardless of license type issued, a private labeler can only be issued a certificate of free sale and sanitation.

(d) Product requirements. Products shall be manufactured in Texas, and/or warehoused, distributed, and sold from Texas. Products shall be available for inspection at the licensed location.

(e) Rule or Act violations. A certificate of free sale and sanitation and/or certificate of origin and sanitation shall not be issued if substantive violations of the applicable Acts or Rules exist as determined by the department. Applicants whose application for a certificate is denied may appeal the decision pursuant to the provisions of §229.307 of this title (relating to Appeal Procedures).

§229.304. Application for Certificate.

(a) Application form. Application forms may be obtained from the Department of State Health Services, or at the website, www.dshs.state.tx.us/fdlicense.

(b) Application information. The application shall be signed and verified, shall be made on an application form authorized by the department, and shall contain the following information:

(1) the name under which the business is conducted and/or licensed;

(2) the address where the business is conducted;

(3) the type of operation conducted by the requesting establishment;

(4) the type of certificate requested; and

(5) the product(s) specified on the application to include the full, common or usual name of the product, the name of the manufacturer and the size of the product. Each product size shall be submitted as a separate product. Products on the certificate will be listed exactly as submitted.

(c) Complete application. Applications shall be completely filled out and shall be accompanied by the appropriate fee. An application is not considered complete unless all information including the correct fee and any supplemental information is submitted and meets all regulatory requirements.

(d) Supplemental information. The labeling information, promotional information, website information, master formulas, marketing clearance letters, distribution records, and advertising affixed to, accompanying, or relating to the products may be required to be submitted for each product upon request by the department. If labeling is in a foreign language, applicant shall provide English translation. Labeling information shall be in final format. Label prototypes and drafts will not be accepted.

(e) Information listed. The certificate will list the product name, the manufacturer's name, and the product size, if applicable.

§229.305. Time Frames.

(a) Time frames for issuing a certificate. The time frames for issuing a certificate shall be as follows.

(1) No later than 15 business days of receipt of a completed application, the department shall issue a certificate, deny a certificate, schedule an inspection, and/or request supplemental information. Time frames are suspended any time the applicant is requested to submit additional information, the applicant submits additional information, or the applicant requests a custom certificate.

(2) No later than 45 business days of receipt of a completed application, the department shall inspect an establishment needing a current compliant inspection, and shall issue the certificate if there is no substantive violation of the Acts or the Rules. If substantive violations exist, the department shall notify the applicant. Time frames are suspended any time substantive violations exist.

(3) No later than 30 business days of receipt of requested supplemental information or acceptable documentation of correction of substantive violations, the department shall review all information for compliance with state and federal regulations. If the information meets the requirements of the state and federal law, the establishment has a current compliant inspection, and all fees have been received, the department shall issue the certificate. Time frames are suspended any time the applicant is requested to submit supplemental information.

(4) If any time frame is suspended for 60 business days or more with no response from the applicant, the application is considered withdrawn.

(b) Expiration dates.

(1) Certificates are valid for the lesser of the term of the license or the inspection interval. Expiration dates are applied on the certificates by the department.

(2) Certificates are invalid immediately upon notice by the department that the facility is not in substantial compliance with all applicable rules and regulations.

§229.306. Fees.

(a) Original certificate. All applicants for certificates shall pay a nonrefundable fee as follows.

(1) \$50 for 1 - 50 products; \$5 for each additional identical certificate.

(2) \$60 for 51 - 200 products; \$6 for each additional identical certificate.

(3) \$75 for 201 - 500 products; \$8 for each additional identical certificate.

(4) \$100 for 501 - 1000 products; \$10 for each additional identical certificate.

(5) \$150 for 1001+ products; \$15 for each additional identical certificate.

(b) Non-licensed establishments. For any establishments not required to be licensed by the department, and that do not have a current compliant inspection, a nonrefundable fee of \$400 for an inspection conducted by department staff will be required in addition to costs outlined in subsection (a) of this section.

(c) Single service container. For single service container establishments regulated by the department, a non-refundable fee will be required as outlined in subsection (a) of this section.

(d) Supplemental information review. For supplemental information review, a separate invoice shall be mailed or sent via facsimile to the applicant. In addition to the fees outlined in subsection (a) of this section, nonrefundable fees of \$72 per hour of review time will be charged with a one-half hour minimum. These fees shall be paid prior to the certificate being issued. Failure to pay the review fee will result in denial of the certificate.

(e) Custom certificates. For a custom certificate, a separate invoice shall be mailed or sent via facsimile to the applicant. In addition to the fees outlined in subsection (a) of this section, a nonrefundable fee of \$72 per hour of review time will be charged with a one-half hour minimum. All applicable fees shall be paid prior to the certificate being issued. Failure to pay all applicable custom certificate fees will result in denial of the certificate.

(f) No transfers. Certificates shall not be transferred from one person to another or from one establishment to another. The forging (by altering, making or reproducing) or tampering with a certificate of free sale and sanitation and/or a certificate of origin and sanitation is prohibited by law. Such conduct is a felony punishable under the Texas Penal Code, §32.21 and §37.10.

(g) Delivery by mail. Certificates issued will be delivered by first class mail through the United States Postal Service. Applicants will be responsible for all costs associated with other means of mailing.

§229.307. Appeal Procedures. Upon denial of a certificate, the applicant will receive a written response outlining the reasons for denial. If the reason for denial is failure to be in substantial compliance with the applicable Acts or Rules, the applicant will receive a notice of violation or other notification from the department. Appeals based on noncompliance issues shall be handled in accordance with the instructions in the notice. An applicant may request in writing a de novo review of the decision to deny a certificate from a representative of the department when the denial is based on any other grounds.